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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/213,834	12/17/1998	YURI (IOURI) ROMANTCHIKOV	99999/400400	6351
26646	7590	11/17/2003	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			MORAN, MARJORIE A	
			ART UNIT	PAPER NUMBER
			1631	18

DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/213,834

Applicant(s)

ROMANTCHIKOV, YURI (IOURI)

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30, 33-38 and 40-68 is/are pending in the application.
- 4a) Of the above claim(s) 33-38, 40, 41 and 51-68 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 42-50 is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-30 in Paper No. 17, filed 5/13/03 is acknowledged. The examiner has determined that claims 42-50 are free of the prior art and appear to be allowable, therefore these claims are rejoined with Group I.

Claims 33-48, 40-41 and 51-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 17.

***Information Disclosure Statement***

The UPCROFT article has been fully considered. Applicant is thanked for providing another copy of the reference. To avoid confusion and possible duplication of the other references cited in the IDS upon printing, consideration of the UPCROFT reference is indicated by its inclusion on a Form 892. The Form 892 is included with this Office Action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 recites joining a nucleic acid fragment with a linearized vector "at a first nucleic acid concentration" in step (a). It is unclear whether the fragment, the vector, or the combination of the two are intended to be at "a first nucleic acid concentration", therefore the claim is indefinite.

Claim 1 also limits "said cohesive circularization ends" to a particular length in the last paragraph of the claim. It is unclear if the antecedent basis for "said cohesive circularization ends" is intended to be the "hybridized cohesive circularization ends" recited in the first line of step (b) or the "single-stranded cohesive circularization ends" recited in the third line of step (b), therefore the claim is indefinite. If all the cohesive circularization ends of the claim are intended to be the same, then it is noted that the claim does not make this limitation clear.

Claim 2 recites joining a nucleic acid fragment with a linearized vector "at a first nucleic acid concentration" in step (a). It is unclear whether the fragment, the vector, or the combination of the two are intended to be at "a first nucleic acid concentration", therefore the claim is indefinite.

Claim 2 also recites the phrase "nucleic acid concentration circularization" in the last line of the claim. Although this may be a typographical error, it is also possible that applicant intends a further limitation with regard to nucleic acid concentration and circularization conditions. It is unclear what limitation applicant intends, therefore the claim is indefinite.

Claim 4 ends with the phrase "and an insertion end". It is unclear whether applicant intends to limit each vector part to comprise a cohesive circularization end and

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an insertion end, or intends each vector part to comprise a cohesive circularization end which can hybridize to a complementary cohesive circularization end and --to-- an insertion end. As the limitation intended by applicant is unclear, the claim is indefinite.

Claim 5 limits a fragment to comprise a "complementary" insertion end and a "complementary" cohesive circularization end, but does not recite what these are intended to be complementary to; e.g. to each other, or to the ends of the linearized vector, or to some other sequence. As the limitations intended by applicant are unclear, the claim is indefinite.

Claim 8 limits a nucleic acid fragment to comprise a "complementary" insertion end and a "complementary" cohesive circularization end, but does not recite what these are intended to be complementary to; e.g. to each other, or to the ends of the linearized vector, or to some other sequence. As the limitations intended by applicant are unclear, the claim is indefinite.

Claims 9-11 recite that cohesive circularization ends "are formed by" recited steps. It is unclear if applicant intends to limit the method of claim 1 to further comprise the steps recited in each of claims 9-11, or intends to limit the circularization ends. If applicant intends to limit the cohesive circularization ends, then it is unclear what structural limitation of the product (i.e. cohesive circularization ends) is intended by the "formation" steps. As the limitations intended by applicant are unclear, the claims are indefinite.

Claim 16 recites limitations of a blunt end and recites that the blunt end be "prepared by" particular steps. It is unclear if applicant intends to limit the method of

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claim 1 to further comprise the steps recited in 16, or intends to limit the blunt ends. If applicant intends the steps to limit the blunt ends, then it is unclear what structural limitation of the product (i.e. blunt ends) is intended by the "preparation" steps. As the limitations intended by applicant are unclear, the claim is indefinite.

Claim 17 recites that a circularization end to comprise 3' overhang which is "prepared by" particular steps. It is unclear if applicant intends to limit the method of claim 1 to further comprise the steps recited in 17, or intends to limit the circularization end. If applicant intends the steps to limit the circularization end, then it is unclear what structural limitation of the product is intended by the "preparation" steps. As the limitations intended by applicant are unclear, the claim is indefinite.

### ***Allowable Subject Matter***

The following is an examiner's statement of reasons for allowance: the prior art neither teaches nor fairly suggests a linearized vector comprising ends covalently linked to a topoisomerase.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

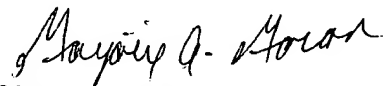
**Conclusion**

Claims 42-50 are allowed. Claims 1-30 are rejected and claims 33-38, 40-41 and 51-68 are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

  
**MARJORIE MORAN**  
**PATENT EXAMINER**

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